

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

EMD MILLIPORE CORPORATION,	)	
MILLIPORE AB, and	)	
MILLIPORE SAS,	)	
	)	
Plaintiffs,	)	CIVIL ACTION NO.
	)	11-10221-DPW
v.	)	
	)	
	)	
ALLPURE TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM AND ORDER

October 11, 2012

Plaintiffs EMD Millipore Corporation, Millipore AB, and Millipore SAS (collectively, "Millipore") brought this action against Defendant AllPure Technologies, Inc. ("AllPure") for infringement of United States Patent No. 6,032,543 (the "'543 Patent"). The '543 Patent relates to a "device for introduction and/or withdrawal of a medium into/from a container, and more particularly to such devices for introduction and/or withdrawal of media into/from a container as are intended for use in areas with very strict requirements on low contamination risks inside the container and/or in the container environment." '543 Patent, col. 1, ll. 5-11.

AllPure responded to Millipore's claim with a counterclaim seeking a declaratory judgment of non-infringement of the '543 Patent and of the invalidity and/or unenforceability of the '543

Patent. Following the completion of fact discovery, the parties have now submitted comprehensive claim construction briefs.

### **I. THE '543 PATENT**

The United States Patent and Trademark Office ("PTO") issued the '543 Patent, entitled "Device for Introduction and/or Withdrawal of a Medium into/from a Container," to Millipore on March 7, 2000. The application was filed on October 18, 1996, and the final patent includes Claims 1 through 14, of which Claim 1 is independent, and the remaining are dependent. '543 Patent col. 9, l. 15-col. 10, l. 61.

The specification explains that, during certain stages in the production of products within fields such as pharmaceuticals and biotechnology, there is a need for continuous sampling of media or for the addition of regulating or active media. *Id.* col. 1, ll. 12-19. "When such production is carried out under conditions of low contamination requirements with respect to the media that are taking part in the process, the production normally is carried out in a sealed container. However, contamination risks arise when a medium is to be added to or a sample be withdrawn from the container." *Id.* col. 1, ll. 19-24.

Prior to the '543 Patent, most means of minimizing contamination risks were ineffective, costly, or both. The '543 Patent aimed to solve these problems through a device that would protect the medium and the environment from contamination,

ensuring that representative samples could be consistently taken and allowing the device to be used anywhere and not just in so-called "clean rooms." *Id.* col. 2, ll. 20-47.

Claim 1 of the '543 Patent, the only independent claim, reads:

1. A device for one of introduction and withdrawal of a medium into a container having an aperture formed therein for receiving said device, said device comprising:

at least one removable, replaceable transfer member for transferring a medium into and out of the container, said transfer member comprising a holder, a seal for sealing said aperture, a hypodermic needle having a tip, said needle supported within said holder in a longitudinal direction thereof, wherein the seal has a first end comprised of a bellows-shaped part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part, said membrane portion for sealing said aperture of said container, wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction, said membrane portion pierceable by the tip of the needle to form a sealable channel;

a fastening device for sealingly securing the transfer member via the seal with the aperture of the container, thereby forming a closed system, said fastening device comprising a flanged part sealingly secured in the aperture and formed with at least one hole therethrough in communication with an interior of said container, a magazine part for removable securement of said at least one transfer member, and a fastening and centering means for removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic

needle for introduction into and withdrawal from the container through the membrane portion and the hole.

*Id.* col. 9, ll. 15-46.

## II. LEGAL BACKGROUND

A patent must include "one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Although questions of patent infringement may be resolved by a jury, "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

### A. Claim Construction

When construing the terms in a claim, the words "'are generally given their ordinary and customary meaning.'" *Phillips*, 415 F.3d at 1312 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996)). The "ordinary and customary meaning" is the meaning that "a person of ordinary skill in the art in question at the time of the

invention" would give to the term, read "in the context of the entire patent, including the specification." *Id.* at 1313. When the ordinary meaning of the language of a claim is readily apparent, claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

If, however, the ordinary meaning is not readily apparent, then a court should look to the patent in conjunction with its prosecution history. *Id.* at 1317. First, a court must "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Next, a court should "review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Id.* At this step, a court may consider the prosecution history, which "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution." *Phillips*, 415 F.3d at 1317. However, the Federal Circuit has warned that because the prosecution history "represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of

the specification and thus is less useful for claim construction purposes." *Id.*

Third, if the claim term remains ambiguous, a court may consider "extrinsic evidence," such as expert testimony, dictionaries, and treatises. *Id.* Although "extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand the claim terms to mean," *id.* at 1319, it is "less reliable than the patent and its prosecution history," *id.* at 1318, and "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence," *id.* at 1319.

B. Means-Plus-Function

Some of the disputed claim elements are alleged to be "means-plus-function" elements implicating ¶ 6 of 35 U.S.C. § 112. That section provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

*Id.* In other words, a claim that recites a "means for" performing a function does not have to state a specific structure for carrying out that function in the claim, so long as it is described in the specification. As a result, "[i]n construing a

means-plus-function claim, the district court must first determine the claimed function and then identify the corresponding structure in the written description of the patent that performs that function." *Baran v. Med. Device Techs, Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010).

The scope of the claim language is of particular concern in identifying the function of a means-plus-function claim. The Federal Circuit instructs that "a claimed function may not be improperly narrowed or limited beyond the scope of the claim language" and "neither may the function be improperly broadened by ignoring the clear limitations contained in the claim language." *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1319 (Fed. Cir. 2003).

### **III. CLAIM CONSTRUCTION**

The parties dispute a number of claim terms, all but one of which come from Claim 1. Millipore seeks to have me construe the terms "bellows-shaped part," "said bellows part," "said bellows-shaped part," "at least one removable, replaceable transfer member," "interiorly formed," "magazine part," and "fastening and centering means" from Claim 1, and "collar" from Claim 3.

AllPure argues that groupings of claim terms need to be construed, and requests constructions of: (1) "removable, replaceable transfer member," and "a magazine part for removable securement of said at least one transfer member," (2) "a first

end comprised of a bellows-shaped part sealingly attached to said holder . . . , wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction," "a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part," and "collar" (from Claim 3), and (3) the "fastening and centering means."

The parties agree that "aperture" should be construed as "opening." They also agree that "said bellows part" and "said bellows-shaped part" should be construed in the same way as "bellows-shaped part" is construed. I now turn to the disputed claim terms.

A. "Removable, Replaceable Transfer Member" and "A Magazine Part for Removable Securement of Said at Least One Transfer Member"

*1. The Parties' Arguments*

AllPure argues that the terms "removable, replaceable transfer member" and "a magazine part for removable securement of said at least one transfer member" in Claim 1 should be read in concert. AllPure contends that "removable, replaceable transfer member" should be construed to mean "a transfer member that can be removed from the magazine part of the device and replaced with another transfer member." AllPure also suggests that the second phrase should be construed to mean that a "magazine part holds one or more transfer members and allows a transfer member to be



removed from the magazine part and replaced with another transfer member."

Millipore argues, however, that the terms to be construed are "at least one removable, replaceable transfer member" and "magazine part." Millipore contends that "at least one removable, replaceable transfer member" should be construed as "one or more transfer members that are capable of being removed from the magazine part and replaced with one or more transfer members." Millipore contends that "magazine part" should be construed as "a part that removably secures at least one transfer member."

## *2. Construction*

The parties agree on two matters of construction. First, the parties agree that a transfer member must be removable and replaceable from a "magazine part."<sup>1</sup> Second, there is no dispute that "at least one" means one or more.

AllPure contends that transfer members must be *individually*, as opposed to collectively, removable. I disagree. True, if there were an embodiment of the device with only one transfer member, that transfer member would necessarily be individually replaceable or removable. But the Claim's recitation of "at

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<sup>1</sup>In prior iterations of their claim construction briefs, the parties had disagreed on whether a transfer member must be removable and replaceable from a "magazine part" or from a "device."

least one removable, replaceable transfer member," '543 Patent, col. 9, ll. 18-20, contains no limitation that additional transfer members function in the same manner as the first, beyond that they too are removable and replaceable. Moreover, AllPure's introduction of the term "*another* transfer member" might be read to suggest that the same transfer member could not be used again after it is removed--a limitation that appears nowhere in Claim 1.

In light of the specification, which merely sought not to limit the precise number of transfer members in any given embodiment, '543 Patent, col. 7, ll. 10-12 ("The number of devices for a container as well as the number of transfer members for each device could, however, differ."), I decline to limit the claim to individual as opposed to collective removal or to different member replacement after removal.

The prosecution history, where Millipore emphasized that under Claim 1 there could be "individual operation of each holder between the inserted or withdrawn positions," does not suggest to the contrary. Independent operation does not necessarily dictate whether removal of transfer members may be accomplished simultaneously or individually, and whether replacement may involve the same or separate members.

Accordingly, I construe the claim "at least one removable, replaceable transfer member" as "at least one transfer member

that can be removed from the magazine part of the device and replaced with at least one removable, replaceable transfer member." Given that construction, the term "magazine part" has the plain meaning of "a part that removably secures at least one transfer member."<sup>2</sup>

B. "A First End Comprised of a Bellows-Shaped Part Sealingly Attached to Said Holder . . . , Wherein Said Bellows-Shaped Part Surrounds Said Needle and is Deformable in a Longitudinal Direction"

*1. The Parties' Arguments*

AllPure argues that "bellows-shaped part . . . deformable in a longitudinal direction" should be construed to mean "a part that has an accordion-like shape when compressed." Millipore contends that "bellows-shaped part" should be construed as "a part in which longitudinal deformation is enabled by at least one plate-like member."

Claim 1 recites "[a] first end comprised of a bellows-shaped part sealingly attached to said holder . . . , wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction." '543 Patent col. 9, ll. 23-30. The specification gives the only additional suggestion as to what

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<sup>2</sup> AllPure's proposed construction of "a magazine part for removable securement of said at least one transfer member" as a "magazine part holds one or more transfer members and allows a transfer member to be removed from the magazine part and replaced with another transfer member" is unnecessary. The meaning of "magazine part" in Claim 1 is plain, especially after construction of "at least one removable, replaceable transfer member" is complete.

"bellows-shaped part" means, directing the reader to Figures 3 and 4. '543 Patent col. 3, ll. 27-31 ("The bellows shaped part 7 . . . may be compressed in the lengthwise direction of the needle 5 between the positions illustrated in FIGS. 3 and 4, respectively.").

AllPure contends that Figure 4 shows that the bellows-shaped part has an accordion-like shape when compressed. Millipore disagrees with AllPure's characterization, and submits an Affidavit of Dr. Alexander Slocum, a professor of mechanical engineering with twenty-nine years of experience designing and specifying bellows. Slocum asserts that a bellows has one or more plate-like members and can be deformed longitudinally in response to forces exerted upon it. He says that the bellows in Figures 3 and 4 of the '543 Patent show "at least one identifiable plate-like member . . . having about one and a half convolutions." According to Slocum, "[w]hile Figures 3 and 4 of the '543 Patent show a bellows-shaped part, neither figure shows an accordion bellows," because accordion bellows "have a regular repeating structure to form many convolutions." Figure 4, highlighting the "bellows-shaped part" marked as (7), is below:

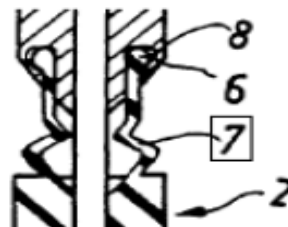


Figure 4

Slocum states that based on his expertise, a review of the '543 Patent and its prosecution history, and an article from 1972 describing half-convolution bellows, "one of ordinary skill in the art at the time the invention in the '543 Patent was made would understand the term 'bellows-shaped part' in Claim 1 of the '543 Patent to mean 'a part in which longitudinal deformation is enabled by at least one plate-like member.'"

## 2. Construction

Neither "plate-like" nor "accordion" appear anywhere in Claim 1, the specifications, or the prosecution history. The only support for construing "bellows-shaped part" as being "plate-like" comes from Slocum's affidavit; the support for construing "bellows-shaped part" as compressing into an "accordion-like shape," is AllPure's interpretation of a series of figures in the '543 Patent.<sup>3</sup>

In the hierarchy of sources for claim construction, intrinsic evidence such as the patent itself, is superior to extrinsic evidence like Slocum's expert affidavit. *Phillips*, 415 F.3d at 1317. Here, however, the only intrinsic evidence of the meaning of "bellows-shaped part" is Figures 3 and 4, which themselves are unexplained. Thus, I turn to extrinsic evidence

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<sup>3</sup>Although it is not explicitly cited, it is possible AllPure takes the "accordion-like shape" limitation from Webster's Third International Dictionary 201 (3d ed. 1986) (defining bellows as "any of various enclosures of variable volume with walls like those of an accordion").

to understand the intrinsic evidence of Figures 3 and 4.

Slocum opines that a person of ordinary skill in the art described in the '543 Patent would be an engineer with three to five years of experience designing devices in which seals play an important role in the product. That person would know that there are two types of seals that allow for motion between parts of a device, sliding and non-sliding seals. Non-sliding seals allow for movement between parts of a device not by relative motion, or "sliding," between the seal and a moving part, but instead by "elastic deformation of the seal as the part moves." A person of ordinary skill in the art, Slocum contends, would know that a bellows is a type of non-sliding seal with "one or more plate-like members" that "will deform in the longitudinal direction in response to axial forces."

Slocum further explains that "[t]wo plate-like members, taken together constitute a bellows 'convolution.' A single plate-like member of a bellows is a half-convolution." Accordingly, Slocum characterizes the bellows-shaped part depicted in Figure 4 as "having about one and a half convolutions." Slocum discredits AllPure's construction by observing that, to the extent that "accordion-like shape" implies a "regular repeating structure," any requirement of regular repetition is contradicted by the irregular shape depicted in Figure 4.

AllPure attempts to rebut Slocum's interpretation by highlighting that Slocum's own textbook does not describe a bellows having only one plate-like structure or a single "half-convolution." But Slocum provides just such an example from an article on air-conditioning compressors, confirming that even a single plate-like member can constitute a "bellows-shaped" part. Any further attempt by AllPure to limit "bellows-shaped parts" to parts consisting of more than one plate-like structure improperly attempts to use Figure 4, which contains several plate-like structures, to narrow claim language that includes no such limitation.

Therefore, given the intrinsic evidence of Figure 4 and Dr. Slocum's affidavit, I construe "bellows shaped part" to mean "a part in which longitudinal deformation is enabled by at least one plate-like member."

C. "A Second End Comprising a Self-Sealing Membrane Portion Interiorly Formed at an End of Said Bellows Part"

1. *The Parties' Arguments*

AllPure argues that "interiorly formed" in Claim 1 should be construed to mean that "the membrane portion of the seal is integral to the bellows-shaped part of the seal to form a single piece." Millipore contends that the phrase should be construed to mean "contained inside a structure."

AllPure supports its construction with arguments from the claim language, the specification, and the prosecution history.

Millipore, relying on Slocum's affidavit, argues that one of ordinary skill in the art would understand "interiorly formed" to mean "contained inside of a structure." Slocum's affidavit, in turn, relies on the fact that Claim 1 does not use the word "integral" in relation to the self-sealing membrane portion of the seal, and the words "interiorly" and "exteriorly" appear elsewhere in the specification of the '543 Patent. For example, the phrases "area which is disposed *interiorly of the interconnection area 50*," '543 Patent col. 7, ll. 63-64 (emphasis added), and "interconnection for instance extended up to or *terminated interiorly of said marginal area 50*," *id.* ll. 59-60 (emphasis added), demonstrate that "interiorly" references the interior or inside of a structure. Likewise, "exteriorly" is used in the phrase "open groove **20** provided in the peripheral surface of the magazine part **17** *exteriorly of the associated aperture 19*," *id.* col. 3, ll. 59-61 (emphasis added), to mean the exterior or outside of a structure.

## 2. Construction

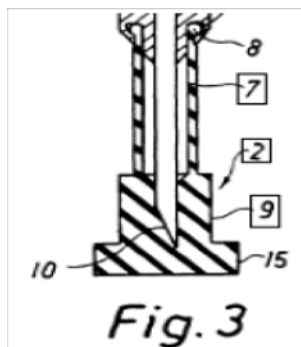
The claim language, specification, and prosecution history demonstrate that aspects of both parties' proposed constructions are correct.

Claim 1 recites a transfer member comprising a holder and a seal, "wherein *the seal has a first end* comprised of a bellows-shaped part sealingly attached to said holder, *and a second end*



comprising a self-sealing membrane portion *interiorly formed at an end of said bellows part.*" '543 Patent col. 9, ll. 20-27 (emphasis added). Thus the plain language of the claim teaches, as AllPure argues, that there are two ends that together form a single seal in the invention.

Figure 3 and the specification confirm that the two ends of the seal are one integral piece. The specification explains that "[t]he seal **2** is formed with an upper-bellows shaped part **7**," and "[a]t its lower end the seal **2** is formed with a membrane portion **9** the upper end of which is sealingly attached to the bellows-shaped part **7**." '543 Patent col. 3, ll. 25-34. In Figure 3, the upper-bellows shaped part (7) and lower membrane portion (9) (the two ends) of the seal (2) are shaded in one identical and continuous manner, which confirms that the two components are integral. See *Millipore Corp. v. W.L. Gore & Assocs., Inc.*, 750 F. Supp. 2d 253, 263 (D. Mass. 2010) (finding that a figure using the same shading pattern for two adjacent pieces "support[s] the presumption that these two elements are part of the same structure"). Figure 3 is below:



I am mindful, however, that the Federal Circuit has repeatedly warned against confining patent claims to specific embodiments in the specification "unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Abbott Labs v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (en banc) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002))).

Although the language of Claim 1 is sufficiently clear in itself, I note that the prosecution history also supports a "clear intention to limit the claim scope" to a seal that must be "attached to the transfer member" in a way that makes the two ends of the seal integral to one another.

Claim 3 of the original patent application stated that the membrane portion is "connected to the bellows-shaped part."<sup>4</sup>

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<sup>4</sup> Claim 3 originally read, in full:

3. A device as claimed in claim 2, characterized in that the transfer member (1) has a holder (4) supporting the hypodermic needle (5), that the seal (2) comprises a bellows-shaped part (7) which is deformable in the longitudinal direction of the needle, said bellows-shaped part (7) surrounding the hypodermic needle (5) and being attached to the holder (4), and in that the seal (2) is formed at its lower end with a membrane portion (9) which is pierceable by the tip (10) of the needle (5) and which is connected to the bellows-shaped part (7) and in use of the device seals said aperture (37).

During the prosecution of the '543 Patent, on September 15, 1999, Millipore "amended Claim 1 to include the limitations of Claim 2-4." After integrating original Claim 3 into what is now Claim 1, Millipore argued to the PTO that it had distinguished its invention from the prior art by adding the description of the seal found in Claim 1 (which came from original Claim 3),<sup>5</sup> and contending that "none of the references show or disclose a seal formed like the present one, which is attached to the transfer member."

Because the claim language clearly describes the seal as one piece with two ends, and because the incorporation of a reading of original Claim 3 (which said that the membrane portion was

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Application May 4, 1998 (emphasis added).

<sup>5</sup> Claim 1 originally read:

1. A device for introduction and/or withdrawal of a medium (39) into/from a container (36) having an aperture (37) formed therein, said device comprising at least one transfer member (1) for transferring medium (39) into or withdrawal of medium from the container (36), and at least one seal (2), wherein the seal (2) is included as a sealingly mounted part of the transfer member (1), in that by means of a fastening device (3) the transfer member (1) is via the seal (2), sealingly secured in the aperture (37) of the container (36) during use of the device (3), during which use it forms a closed system together with the container (36) whereas the transfer member (1) is removable for replacement thereof after use, and in that the seal (2) is formed with a sealable channel for interconnecting the transfer member (1) with the interior of the container (36) during use.

Application, May 4, 1998.

"connected to the bellows-shaped part") into Claim 1 (in the phrasing a "membrane portion interiorly formed at an end of said bellows part") confirms my reading of the claim language, I find the membrane cannot be separate from the bellows-shaped part, as reflected in Millipore's disclaimer of any invention in which the entire seal is not attached to the transfer member itself.<sup>6</sup>

Common sense also supports this construction; without an integral membrane within the ends of the seal, the '543 Patent's objective to provide a contamination-free method of taking samples would be thwarted. See '543 Patent, col. 2, ll. 20-29.

While there is ordinarily a "presumption that the same terms appearing in different portions of the claims should be given the same meaning," as Millipore argues, that presumption does not apply if "it is clear from the specification and prosecution history that the terms have different meanings at different

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<sup>6</sup> Millipore cites *Rambus Inc. v. Infineon Technologies Ag*, 318 F.3d 1081, 1089-91 (Fed. Cir. 2003), and *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1054 (Fed. Cir. 1989), but these cases are inapposite. *Rambus* and *Intervet* admonished against limiting claims based on inaccurate descriptions of those claims by a prosecuting attorney. More specifically, *Rambus* and *Intervet* involved a prosecuting attorney's misstatement that a limitation was added to all claims when, in fact, the limitation was added only to certain claims. Millipore has identified so such inaccuracy in the recited prosecution history, and AllPure makes no attempt to import limitations from other claims in the '543 Patent into Claim 1 based on the prosecution history. It appears, then, Millipore cites these cases for the more basic proposition that the prosecution history should not be used to impose limitations not present in the claim language. True enough, but I have done no such thing. Rather, the prosecution history only helps confirm what I already take to be plain in the claim language.

portions of the claims." *Fin Control Sys. Pty, Ltd. v. OAM, Inc.*, 265 F.3d 1311, 1318 (Fed. Cir. 2001).

Moreover, "interiorly" may still refer in all instances to the interior or inside of a structure, such that AllPure's construction does not necessarily give an inconsistent meaning to "interiorly." The use of "interiorly formed" in Claim 3, in the context of describing a singular seal with two ends, merely adds a requirement of connectedness not present in the use of phrases like "terminated interiorly" or "disposed interiorly" elsewhere in the patent.

Thus the claims, the specification, and the prosecution history demonstrate Millipore's clear intent to use the phrase "interiorly formed at an end of said bellows part" not merely to describe where the membrane portion is located ("inside" the structure, as Millipore contends), but also to disclaim multi-part seals that are not integral to the membrane portion. However, to avoid any ambiguity in words like "integral" and "single piece"--which appear nowhere in the patent--I will use the specification's phrase: "sealingly attached." '543 Patent, col. 3, l. 33.

Accordingly, I construe "interiorly formed" to mean "sealingly attached to the bellows-shaped part and contained inside a structure." For clarity, the entire phrase "a self-sealing membrane portion interiorly formed at an end of said bellows part" is thus construed as "a self-sealing membrane

portion sealingly attached to the bellows-shaped part and contained inside a structure at an end of said bellows part."

D. Collar

*1. The Parties' Arguments*

AllPure argues that "collar" in Claim 3, which is an additional limitation to the seal discussed above, should be construed as "a band that projects from around the bottom of the membrane portion whose diameter is greater than the diameter of the bellows-shaped part of the seal." Millipore contends that "collar" should be construed as "an outer portion of the membrane portion." In the context of Claim 3, Millipore concedes that it is axially clampable.

*2. Construction*

Claim 3 reads, in full: "The device as claimed in claim 2, wherein the membrane portion is formed with a bottom collar that is clamped between the flanged part and the magazine part when in a locked position." '543 Patent col. 9, ll. 53-56. That, as Millipore concedes, the collar in Claim 3 must be axially clampable imports the concept that the collar portion of the membrane must be able to be compressed against the flanged part when the magazine part is clamped to the flanged part. As AllPure notes in support of its construction, "[t]his would not be possible if the collar were no wider than the bellows shaped part." AllPure argues that

Specifically, the bellows shaped part fits within the aperture (19) when the magazine part is clamped to the flanged part. If the collar were no wider than the bellows shaped part, it would also fit into the aperture and would not be "axially clampable," as Millipore suggests. For this reason, the diameter of the collar must be greater than the diameter of the bellows shaped part.

The relevant portions of Figures 1 and 3, showing the magazine part, bellows-shaped part, and apertures, are below:

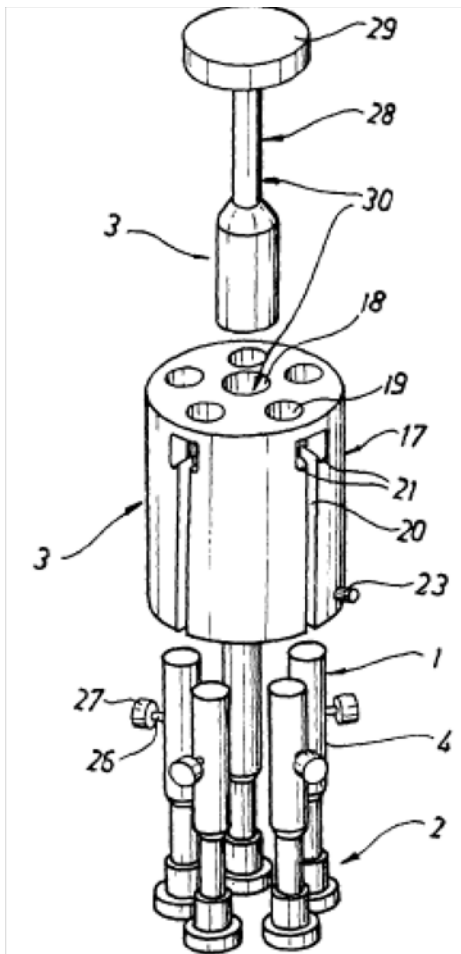


Figure 1

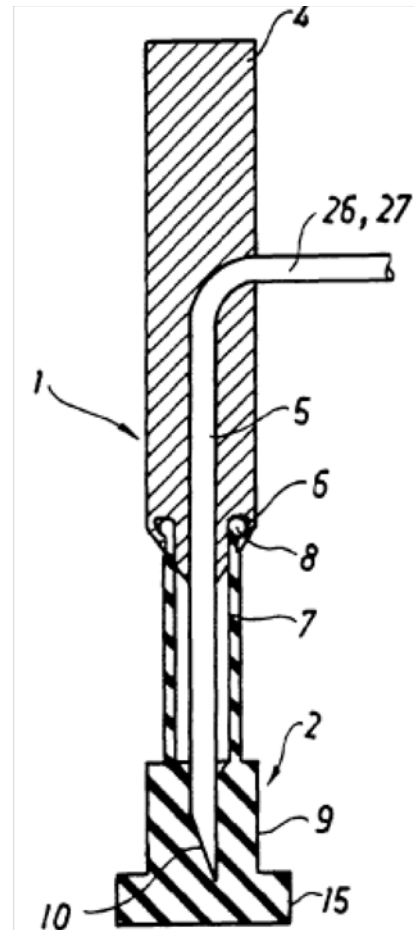


Figure 3

AllPure's interpretation is confirmed by the specification, which describes how "the magazine part 17 is formed with five

through apertures **19** . . . having a diameter-size corresponding to or slightly exceeding the diameter-sizes of . . . the bellows-shaped part **7**, . . . but being smaller than the diameter of the collar **15**." '543 Patent col. 3, ll. 52-58.

Millipore's proposed construction---"an outer portion of the membrane portion"---while employing more words, would be just as ambiguous as the term "collar." I therefore construe "collar" to mean "an axially-clampable outer portion of the membrane portion." Although Millipore has not explained how the collar may be axially clampable if its diameter is less than (or even equal to) that of the bellows-shaped part, this construction reserves that possibility as a matter of fact.

#### E. Fastening and Centering Means

AllPure seeks to have the phrase "fastening and centering means" construed as means-plus-function language pursuant to 35 U.S.C. § 112, ¶6. Millipore argues that the phrase is not means-plus-function language, because there is sufficient structure recited in the claim. Instead, Millipore contends that the phrase should be construed according to its plain meaning, which is "any structure that succeeds in removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole."



Claim 1 requires "a fastening and centering means for removable locking of the magazine part to a flanged part . . . ."

'543 Patent col. 9, ll. 39-41. When a claim limitation uses the word "means," it invokes a rebuttable presumption that 35 U.S.C. § 112, ¶ 6 applies. This presumption can be rebutted if "the claim recites sufficient structure for performing the described functions in their entirety." *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008). "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." *Id.* at 1259-60.

Millipore points to Claim 1 as providing sufficient structure to obviate the need for means-plus-function analysis. The relevant portion of Claim 1 discusses the "fastening device" to which the "fastening and centering means" applies:

a fastening device for sealingly securing the transfer member via the seal and the aperture of the container, thereby forming a closed system, said fastening device comprising a flanged part sealingly secured in the aperture and formed with at least one hole therethrough in communication with an interior of said container, a magazine part for removable securement of said at least one transfer member, and a fastening and centering means for removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole.

'543 Patent col. 9, ll. 33-46. Millipore contends that the above

paragraph makes clear that there are three parts of the claimed "fastening device": (1) "a flanged part," (2) "a magazine part," and (3) "a fastening and centering means." Thus, Millipore argues, the fastening and centering means'

structure is sufficiently identified by the description of the "flanged part" and the "magazine part" and the requirement that the fastening and centering means removably lock the magazine part, with its stated structure, to the flanged part, with its stated structure, "in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole."

Millipore finds more structure in this language than the claim will bear. The claim limits the outer bounds of what the structure of the fastening and centering means could be, based on its ultimate function of locking down the magazine part to the flanged part. But no specific structure that performs the functions of fastening and centering is described in Claim 1. Therefore the presumption that means-plus-function analysis applies remains un rebutted, and I undertake the requisite two-step analysis.

*1. Function*

At argument on construction issues, the parties agree that if "fastening and centering means" needs to be construed under the means-plus-function rubric, and the court splits the analysis of the structure of the "fastening means" and the "centering means"--as I do, below--then the function should also be split

and construed as follows. The function of the "fastening means" is "removable locking of the magazine part to a flanged part to sealingly abut the membrane portion against the hole of the flanged part." The function of "centering means" is "locating the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole."

## 2. *Structure*

Under the second step, the parties disagree about what the corresponding structure would be, pursuant to 35 U.S.C. § 112, ¶ 6, for either the "fastening means" or the "centering means."

### i. *Fastening Means*

AllPure argues that "fastening means" is defined in the '543 Patent, and therefore seeks to have "fastening means" construed as "the stub axle, the channel through the magazine part, and the locking part." Millipore contends that "fastening means" should be construed as "threaded fasteners such as a threaded stub axle and mating threaded knob or locking part, or equivalents thereof."

Claim 1 does not provide clues as to the structure of the fastening means, so I look to the specification for guidance. The specification notes that the "fastening device **3** comprises a locking part, generally designated by **28**, said locking part being

formed at its upper end with a knob **29** and at its lower end with a threaded bore (not shown) into which the stub axle **16** may be screwed. The stub axle **16**, the channel **18**, and the locking part **28** together form a device fastening means, generally designated by reference **30**." '543 Patent col. 4, ll. 16-23.

Other portions of the specification note that the stub axle (16), for example, has "a threaded upper end," *id.* col. 3, ll. 46-47; the locking part (28) has, at its lower end, a "threaded bore into which the stub axle **16** may be screwed," *id.* col. 4, ll. 18-20.

Although the specification thus provides a fairly detailed structure, the preamble to Claim 1 also notes that "certain deviations from the descri[b]ed embodiment may be made. For instance the number of parts and the configuration of the fastening device **3** may be varied." '543 Patent col. 9, ll. 1-4. So, in Millipore's example, it does not matter whether the stub axle or the locking part contain the male or female threads. Additionally, there is room for variation in the precise number of parts involved. But this language essentially reserves equivalents of the structure defined in the specification, to which Millipore is already entitled under 35 U.S.C. § 112, ¶ 6.

Thus, I construe "fastening means" as "a stub axle and locking part, which are able to attach by extending through a channel in the magazine part, and equivalents thereof."

ii. Centering Means

AllPure argues that "centering means" is defined in the '543 Patent, and therefore construes "centering means" as "the pin projecting essentially perpendicularly from the lower part of the peripheral surface of the magazine part." Millipore contends that the structure for the "centering means" should be construed as "annular means matching the cross-sectional area of the magazine part, and a pin or other protrusion and a slit, or equivalents thereof."

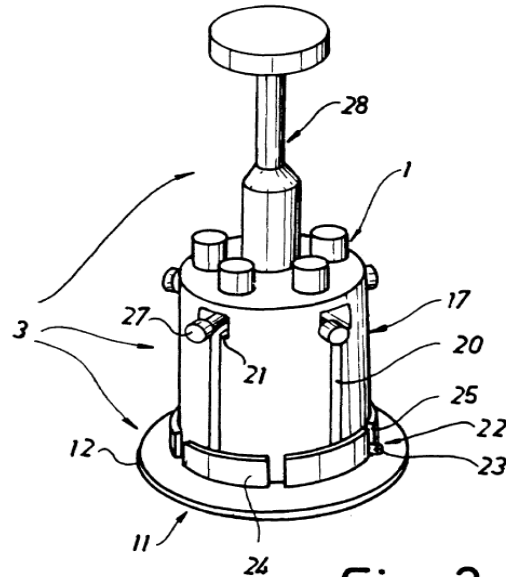
The claim language does not provide clues as to the structure of the centering means, so I look to the specification for guidance. The specification notes that "[t]he centering means **22** comprises at least one pin **23** projecting essentially perpendicularly from the lower part of the peripheral surface of the magazine part **17**." '543 Patent, col. 3, ll. 66-67. AllPure proposes that I adopt this construction of the structure of "centering means."

But Millipore convincingly argues that the specification discloses additional variations for the centering means. For example, as noted above, the preamble to Claim 1 states that "certain deviations from the descri[b]ed embodiment may be made. For instance the number of parts and the configuration of the fastening device **3** may be varied." '543 Patent col. 9, ll. 1-4. Column 3 of the specification also states that

The magazine part **17** and the flanged part **11** have a centering means generally designated by **22** (see FIG. 2). The centering means **22** comprises at least one pin **23** projecting essentially perpendicularly from the lower part of the peripheral surface of the magazine part **17**. The flanged part **11** is formed on its upper face with an annular means **24** matching the cross-sectional area of the magazine part **17** so as to fit the exterior of the latter. The annular means **24** is formed with at least one slit **25** into which the pin **23** may be inserted.

'543 Patent col. 3, l. 63 - col. 4, l. 5 (emphasis added).

Column 4 notes that "[t]he annular means **24**, the pin **23** and the slit **25** co-operate to center the magazine part **17** in such a manner that the hypodermic needle **5** of each transfer member **1** will be positioned straight above a corresponding hole **13**."<sup>7</sup> *Id.* col. 4, ll. 61-65. Figure 2 from the '543 Patent is below:



*Fig. 2*

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<sup>7</sup> Annular is defined as "of or relating to a ring:forming a ring:shaped like a ring." Webster's New International Dictionary 88 (3d ed. 1986).

These details match the function of the centering means, which, as noted above, the parties agree is "removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole."

I therefore construe "centering means" as "a ring-shaped structure matching the cross-sectional area of the magazine, with at least one slit and at least one pin projecting essentially perpendicularly from the lower part of the peripheral surface of the magazine part, and equivalents thereof."

#### **IV. CONCLUSION**

For these reasons, I construe the claim terms the parties dispute as reflected in the "Court's Construction" column of the Chart of Constructions attached hereto. On or before October 19, 2012 the parties shall submit to the court a proposed schedule for completion of discovery and submission of summary judgment papers.

/s/ Douglas P. Woodlock  
DOUGLAS P. WOODLOCK  
UNITED STATES DISTRICT JUDGE

**Chart of Constructions**

<b>Term</b>	<b>AllPure</b>	<b>Millipore</b>	<b>Court's Construction</b>
"at least one removable replaceable transfer member"	[at least one] "transfer member that can be removed from the magazine part of the device and replaced with another transfer member"	"one ore more transfer members that are capable of being removed from the magazine part and replaced with one or more transfer members"	"at least one transfer member that can be removed from the magazine part of the device and replaced with at least one removable, replaceable transfer member"
"a magazine part for removable securement of at least one said transfer member"	a "magazine part holds one or more transfer members and allows a transfer member to be removed from the magazine part and replaced with another transfer member"	"a part that removably secures at least one transfer member"	"a part that removably secures at least one transfer member"
"bellows-shaped part"	"a part that has an accordion-like shape when compressed"	"a part in which longitudinal deformation is enabled by at least one plate-like member"	"a part in which longitudinal deformation is enabled by at least one plate-like member"



Term	AllPure	Millipore	Court's Construction
"interiorly formed"	"the membrane portion of the seal is integral to the bellows-shaped part of the seal to form a single piece"	"contained inside a structure"	"sealingly attached to the bellows-shaped part and contained inside a structure"
"collar"	"a band that projects from around the bottom of the membrane portion whose diameter is greater than the diameter of the bellows-shaped part of the seal"	"an outer portion of the membrane portion"	"an axially-clampable outer portion of the membrane portion"
"fastening means"	"the stub axle, the channel through the magazine part, and the locking part"	"threaded fasteners such as a threaded stub axle and mating threaded knob or locking part, or equivalents thereof"	"a stub axle and locking part, which are able to attach by extending through a channel in the magazine part, and equivalents thereof"

Term	AllPure	Millipore	Court's Construction
"centering means"	"the pin projecting essentially perpendicularly from the lower part of the peripheral surface of the magazine part"	"annular means matching the cross-sectional area of the magazine part, and a pin or other protrusion and a slit, or equivalents thereof"	"a ring-shaped structure matching the cross-sectional area of the magazine, with at least one slit and at least one pin projecting essentially perpendicularly from the lower part of the peripheral surface of the magazine part, and equivalents thereof"